IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH) [redacted] [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	**PUBLIC VERSION** **Confidential Version Filed: January 12, 2024** **Public Version Filed: January 19, 2024**

RESPONSIVE CONCISE STATEMENT OF FACTS IN SUPPORT OF SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S OPPOSITION TO NS'S MOTIONS FOR SUMMARY JUDGMENT

[redacted]

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[redacted]

TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'361 Patent	U.S. Patent No. 9,708,361
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
Bold and Italic	Emphasis added unless indicated otherwise
Br-1	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 1 Regarding Invalidity of the UWA Patents (D.I. 400)
Br-2	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 2 Regarding Infringement of Certain NS Patents (D.I. 403)
Br-3	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 3 Regarding Its Breach of Contract Claim (D.I. 406)
Br-4	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 4 Regarding No Anticipation (D.I. 410)
Br-5	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 5 Regarding No Inequitable Conduct (D.I. 415)
DMD	Duchenne muscular dystrophy
Ex. ____	Exhibit ____[1]
MCA	Mutual Confidentiality Agreement (D.I. 2-1)
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322

[1] Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Oppositions to Plaintiff/Counter-Defendants' Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Steven F. Dowdy, Ph.D. and Andrew Hirshfeld.

[redacted]

Abbreviation	Description
PMO	Phosphorodiamidate morpholino oligomer
Popplewell 2010	Popplewell, et al., Comparative analysis of antisense oligonucleotide sequences targeting exon 53 of the human DMD gene: Implications for future clinical trials, 20 NEUROMUSCULAR DISORDERS 102–110 (2010)
Popplewell '212	U.S. Patent Publication No. 2010/0168212
POSA	Person of ordinary skill in the art
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
Sazani 2010	Sazani, P., et al., Safety Pharmacology and Genotoxicity Evaluation of AVI-4658, *Int'l J. of Toxicology*, 29(2):143-156 (2010)
Sazani '586	International Patent Publication No. WO 2010/048586
Sazani '591	U.S. Patent Application Publication No. US2010/0130591
RSOF	Responsive Concise Statement of Facts in Support of Sarepta Therapeutics, Inc. and the University of Western Australia's Opposition to NS's Summary Judgment Motions
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827

[redacted]

Defendant Sarepta Therapeutics, Inc. ("Sarepta") respectfully submits the following response to Plaintiff's Statement of Facts in support of Plaintiff's Motions for Summary Judgment Nos. 1-5. Sarepta disputes any alleged fact unless it is specifically undisputed below. Sarepta further disputes the arguments that Plaintiff provides in its headings but has not provided a separate response because Plaintiff did not provide evidence in support. Sarepta submits additional facts in support of its Opposition to Plaintiff's motions.

I. *OPPOSITION TO NS'S MOTION #1*: INVALIDITY OF THE UWA PATENTS

A. Sarepta's Responses to Plaintiff's Concise Statement

1. **Undisputed**. However, Sarepta disputes the relevance of whether the specification discusses "nucleobase . . . modifications or substitutes" or "chemically linking . . . one or more moieties or conjugates" to the claims of the Wilton Patents. The claims of the Wilton Patents require that each of the claimed antisense oligonucleotides ("ASOs") must have thymine bases in place of uracil bases. *See, e.g.*, D.I. 417-1 (Ex. 1), claims 1 & 2; D.I. 248 at 25-29. The claims of the Wilton Patents do not recite that the claimed ASOs are "chemically linked to one or more moieties or conjugates that enhance the activity, cellular distribution or cellular uptake of the oligonucleotide." *See, e.g.*, D.I. 417-1 (Ex. 1), claims 1 & 2.

2. **Disputed**. Table 1A of the Wilton Patents includes 211 ASOs targeted to various exons of the human dystrophin pre-mRNA. *See* D.I. 417-1 (Ex. 1), Table 1A. Eight (8) compounds listed in Table 1C are so-called "weasel" compounds, each "joining two or more antisense oligonucleotide molecules," that are not encompassed by the Wilton Patents due to their length, among other reasons. *See id.*, Table 1C, 4:56-62; D.I. 427-2, ¶¶63-65.

Sarepta also disputes that "[t]he specification ***describes a single AO***." The specification of the Wilton Patents discloses a discrete region of exon 53 of the human dystrophin pre-mRNA between positions 23 to 69 that is amenable to exon 53 skipping induced by ASOs, i.e., the "hot

[redacted]

spot." *See* D.I. 417-1 (Ex. 1), Table 39; D.I. 427-2, ¶¶67, 74; Br-1 at 13 n.6. The specification further states that "the invention provides antisense molecules capable of binding to a selected target to induce exon skipping." D.I. 417-1 (Ex. 1), 4:44-46.

NS's statement that "the UWA Patents do not disclose an AO targeting positions +36+60 or an AO targeting positions+36+56" cites no evidentiary support, which violates the requirements set forth in the Scheduling Order. D.I. 143, Paragraph 13(b) ("Each fact . . . shall be supported by specific citation(s) to the record."). Further, the Wilton Patents describe a group of ASOs targeting the exon 53 hot spot, including Sarepta's Vyondys 53® and NS's Viltepso® products, both of which target the hot spot and meet the claimed structural features. *See* D.I. 427-2, Exhibit C, Table 3 n.1, Table 7 n.2; *see also* Ex. 7, 27:18-28:8, 28:19-25, 31:2-6; Ex. 5, 124:11-125:2, 193:17-22.

3. **Disputed**. NS cites no evidentiary support in Paragraph 3, which violates the requirements set forth in the Scheduling Order. D.I. 143, Paragraph 13(b) ("Each fact . . . shall be supported by specific citation(s) to the record."). Further, Sarepta responds to (1)-(9) as follows:

(1)-(2): The specification states that exon skipping ASOs can be made with a "morpholino" backbone having thymine bases in place of uracil bases. *See* D.I. 417-1 (Ex. 1), Table 1A. Contemporary studies demonstrated that the exon skipping ability exhibited by a 2'-O-methyl phosphorothioate ASO is generally translatable to a corresponding morpholino ASO. *See* D.I. 427-2, ¶70. Morpholino ASOs as of 2005 were almost always synthesized with naturally occurring bases. *See id.*, ¶57 n.6.

(3)-(5): The specification discloses testing of exon 53 targeting ASOs that are 20 to 31 bases in length. *See* D.I. 417-1 (Ex. 1), Table 39; D.I. 427-2, ¶74. The specification states that "[w]ith some targets such as exon 19, antisense oligonucleotides as short as 12 bases were able to induce exon skipping, albeit not as efficiently as longer (20-31 bases) oligonucleotides." D.I. 417-1 (Ex. 1),

[redacted]

23:63-66; D.I. 427-2, ¶74. Consistent with the teaching of the Wilton Patents, the tested ASOs are 100% complementary to their target regions. D.I. 417-1 (Ex. 1), 25:21-38; D.I. 427-2, ¶74.

(6)-(7): Sarepta disputes the relevance for the same reasons discussed in response to Paragraph 1.

(8)-(9): Sarepta disputes that whether the word "hot spot," "hotpot" [sic] or "hot-spot" appears in the Wilton Patents is relevant. A POSA reading the specification would have recognized the hot spot, which is a colloquial term for an "area where the oligonucleotides have high activity"—like the discrete region within exon 53 amenable to exon skipping disclosed in the Wilton Patents. *See* D.I. 427-2, ¶74; Ex. 11, 71:25-72:17; Ex. 7, 222:13-223:21. NS also accepts for purposes of its motion that "a POSA would view the [Wilton] Patents as identifying a 'hot spot.'" Br-1 at 13 n.6.

4. **Disputed**. The specification's statement in Paragraph 4 is taken out of context because the full sentence states: "With some targets such as exon 19, antisense oligonucleotides as short as 12 bases were able to induce exon skipping, ***albeit not as efficiently as longer (20-31 bases) oligonucleotides.***" D.I. 417-1 (Ex. 1), 23:63-66; *see* D.I. 427-2, ¶74. Dr. Dowdy's testimony in Paragraph 4 is also taken out of context, and does not support NS's statement. Dr. Dowdy explains [redacted] *See* D.I. 427-2, ¶128.

5. **Disputed**. The evidence cited in Paragraph 5 does not support NS's statement of fact regarding the "formula (4^n) x (n+1)." This formula, used by Dr. Hastings (D.I. 427-5, ¶48), ignores multiple claim limitations. *See* D.I. 427-2, ¶¶32-45; RSOF ¶1.9. The formula does not

[redacted]

estimate "[t]he number of species encompassed by the claims of the UWA Patents."

Dr. Dowdy's testimony in Paragraph 5 is taken out of context, and does not support NS's statement of fact. NS omits additional testimony from Dr. Dowdy, [redacted] Ex. 11, 197:10-198:20.

NS's reference to the prosecution history of the '851 Patent does not account for contextual differences, i.e., the formula was used in a ***different*** context (an obviousness rejection), was based on a ***different*** disclosure ("prior art"), and at a ***different*** timepoint (before the Wilton Patents). D.I. 428-6, SRPT-VYDS-0004783. In addition, NS omits that the PTO determined that the claim scope estimated using this formula was "overly speculative." Ex. 17, 24.

6. **Disputed**. NS's statement of fact in Paragraph 6 does not accurately reflect Dr. Dowdy's testimony. *See* D.I. 427-2, ¶37 n.4. In addition, [redacted] *See* D.I. 427-2, ¶¶56-58. Dr. Hastings' calculations, however, did not differentiate the '851 Patent from the '590 and '827 Patents, and instead "assumed randomness" across all three Wilton Patents. D.I. 427-5, ¶48; Ex. 4, 96:20-97:5.

7. **Disputed**. Neither in his deposition nor in his reports did Dr. Dowdy ever mention [redacted] stated in Paragraph 7. *See* D.I. 427-2, ¶¶56-58; Ex. 11, 203:2-6. NS cites no evidentiary support for these numbers in Paragraph 7, which violates the requirements set forth in the Scheduling Order. D.I. 143, Paragraph 13(b) ("Each fact . . . shall be supported by specific citation(s) to the record.").

[redacted]

Further, Dr. Dowdy's calculations [redacted] *See* D.I. 427-2, ¶59. To the extent that the math of NS's counsel is based on those calculations, it does not support NS's statement that there are "at least 90,344 ('851 Patent) or 177,624 ('590 and '827 Patents) [ASOs] falling within the scope of the claims of the UWA Patents."

8. **Disputed**. The evidence cited in Paragraph 8 does not support NS's statement of fact. In allowing "up to 19 mismatches," Dr. Hastings ignored multiple claim limitations. *See* D.I. 427-2, ¶¶32-45; RSOF ¶1.9. Dr. Hastings did not "apply[] the Court's construction."

Further, as Dr. Dowdy explained, [redacted] Ex. 11, 36:3-17. [redacted] D.I. 427-2, ¶¶35-41, 37 n.4.

9. **Disputed**. NS's statement of fact in Paragraph 9 does not accurately reflect Dr. Dowdy's testimony regarding his claim scope analysis. Dr. Dowdy explained that [redacted] *See* D.I. 427-2, ¶57 n.6. Dr. Dowdy's approach is consistent with that of Dr. Hastings, [redacted] D.I. 427-5, ¶48 n.2. NS's statement of fact that the "true number of candidates is a few fold higher" is unsupported because Dr. Hastings' "a few fold higher" assertion is unsupported. *See* Ex. 427-7, ¶14 n.2.

[redacted]

10. **Disputed**. The quotes from the Response to Office Action reproduced in Paragraph 10 are taken out of context. Each of the quotes generically refers to exon skipping ASOs or relates to ***non***-exon 53 skipping ASOs. *See* D.I. 428-6, SRPT-VYDS-0004784, -4790-4795 (human exon 2, 29, 43, 46, 48, 50 or murine exon 23). These quotes are also from statements made in response to an obviousness rejection, which "does not take into account . . . disclosure in the rejected patent application." *See id*., SRPT-VYDS-0004783; Ex. 6, 195:19-196:14; *see also id*., 196:15-197:2.

11. **Disputed**. The quotes from the Response to Office Action reproduced in Paragraph 11 are taken out of context for the same reasons discussed above in response to Paragraph 10.

12. **Disputed**. The quotes from UWA's motion reproduced in Paragraph 12 are taken out of context. Each of the quotes generically refers to exon skipping ASOs or relates to ***non***-exon 53 skipping ASOs. *See* D.I. 427-23, 4-9 (discussing ASOs directed to human exon 50, 51, or murine exon 23). In addition, these quotes are from statements made in evaluating written description and enablement support for the claims of U.S. Application No. 11/233,495, assigned to Academisch Zeikenhuis Leiden, the disclosure and the claims of which are different from the disclosure and the claims of the Wilton Patents. *See id.*, 9-10.

13. **Disputed**. The quotes from UWA's motion reproduced in Paragraph 13 are taken out of context for the same reasons discussed above in response to Paragraph 12.

14. **Disputed**. Dr. Dowdy's testimony is taken out of context because NS omits [redacted] Ex. 11, 44:4-15. His testimony in Paragraph 14 also explains [redacted]

[redacted]

[redacted]. *See id.*, 25:9-19. Dr. Dowdy's testimony says nothing about [redacted]

15. **Disputed**. The quote from UWA's motion reproduced in Paragraph 15 is taken out of context. The quote and statement from the Wilton Patents acknowledge the importance of the empirical testing. But NS omits that empirical testing is in fact disclosed in the Wilton Patents for exon 53 targeting ASOs—empirical testing that identified the exon 53 hot spot. *See* D.I. 417-1 (Ex. 1), Table 39; D.I. 427-2, ¶¶74, 267. The materials cited by NS say nothing about "the need to test each and every potential AO to determine ***whether an AO falls within the scope of the claims***."

[redacted]

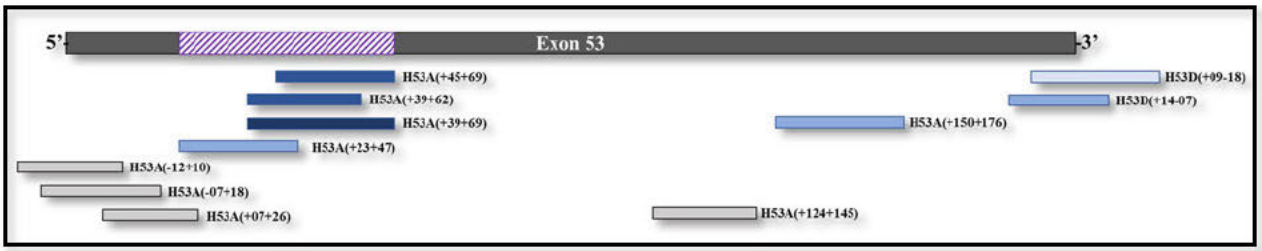
B. Sarepta's Concise Counterstatement of Facts

1. The Shared Specification of the Wilton Patents

1.1. Before the Wilton Patents were filed in June 2005, there was no known specific region within exon 53 of the human dystrophin pre-mRNA that researchers could target with ASOs to indue exon skipping. D.I. 427-2, ¶333; Ex. 3, ¶18.

1.2. The Wilton Patents identified a discrete region of exon 53 of the human dystrophin pre-mRNA amenable for exon skipping, which spans from positions 23 to 69. D.I. 427-1, ¶¶97-101; D.I. 427-2, ¶74; Ex. 7, 222:13-223:21; Br-1 at 13 n.6. The region was identified based on testing of exon 53 targeting ASOs that are 20 to 31 bases in length. D.I. 417-1 (Ex. 1), Table 39; D.I. 427-2, ¶74. Four tested ASOs are reported to induce exon 53 skipping: H53A(+23+47), H53A(+39+62), H53A(+39+69), and H53A(+45+69). D.I. 417-1 (Ex. 1), Table 39; D.I. 427-2, ¶74.

1.3. This discrete region is colloquially called a "hot spot," which, by definition, is an "area where the oligonucleotides have high activity." D.I. 427-1, ¶99; Ex. 7, 71:25-72:17. Dr. Dowdy provided the following graphic illustrating the hot spot identified in the Wilton Patents (*see* D.I. 427-1, Figure 16[2]):



1.4. To date, two ASOs have been approved by FDA for treating Duchenne muscular

[2] The purple hashmarks are added in accordance with Dr. Dowdy's other graphics. D.I. 427-2, ¶336 ("the hot spot that Dr. Wilton and his co-inventors identified (purple hashmarks)"); *see also* D.I. 427-1, ¶99 ("used different shades of blue" to indicate exon skipping at varying concentrations).

[redacted]

dystrophy in patients with mutations amenable to exon 53 skipping—Sarepta's Vyondys 53® (golodirsen) and NS's Viltepso® (viltolarsen). *See* D.I. 427-1, ¶¶126-127. The active ingredient of Sarepta's Vyondys 53® is a morpholino ASO targeting positions 36 to 60. *Id.*, ¶¶128-133. The active ingredient of NS's Viltepso® is a morpholino ASO targeting positions 36 to 56. *Id.*, ¶¶138-139. Dr. Wilton testified that [redacted] Ex. 7, 27:18-28:8, 28:19-25, 31:2-6. Dr. Fletcher also testified that [redacted] Ex. 5, 124:12-125:2, 193:17-22.

1.5. The Wilton Patents provide guidance for designing, synthesizing, and testing exon 53 targeting ASOs. *See* D.I. 427-2, ¶¶239-249. Methods of synthesizing and testing ASOs were also known in the art. *See id.*, ¶¶233-237; D.I. 427-5, ¶43; Ex. 4, 229:15-17 (morpholino ASOs were "commercially available" in 2005).

2. The Wilton Patents Read by a POSA

1.6. The claims of the Wilton Patents recite the following common structural features regarding the claimed oligonucleotides: (1) "antisense oligonucleotide"; (2) "20 to 31 bases"; (3) "comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA"; (4) "the base sequence comprises at least 12 consecutive bases" SEQ ID NO: 195; (5) "in which uracil bases are thymine bases"; and (6) "wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide." D.I. 427-2, ¶66. In the case of the '851 Patent, the claims further require that the target region of the claimed ASO is within positions 23 to 69. *Id.*

1.7. These structural features collectively identify a limited group of ASOs potentially encompassed by the Wilton Patents. *See id.*, ¶57. A POSA would have understood that most, if not all, of those ASOs would induce exon 53 skipping because they target the exon 53 hot spot. *See*

[redacted]

id., ¶¶67-68. From the Wilton Patents, a POSA would have identified these claimed structural features that correlate with the claimed function of exon 53 skipping. *Id*., ¶74.

1.8. Dr. Dowdy explained that [redacted] D.I. 427-2, ¶37 n.4. The Wilton Patents state: "'[S]pecifically hybridisable' and 'complementary' are terms which are used to indicate a sufficient degree of complementarity or precise pairing such that stable and specific binding occurs between the oligonucleotide and the DNA or RNA target." D.I. 417-1 (Ex. 1), 25:21-38. The Wilton Patents further state that there must be "a *sufficient degree of complementarity* to avoid non-specific binding of the antisense compound to non-target sequences under conditions in which specific binding is desired." *Id.*

1.9. Dr. Hastings' competing claim scope analysis ignored multiple claim limitations. *See* D.I. 427-5, ¶¶46-48; D.I. 427-2, ¶¶32-45. Dr. Hastings did not evaluate the '851 Patent separately from the '590 and '827 Patent, even though the '851 Patent additionally requires that the claimed target region is within positions 23 to 69. *See* D.I. 427-5, ¶¶46-48. Dr. Hastings admitted: "[redacted]" *Id.*, ¶45. In deposition, Dr. Hastings also admitted that "[redacted]" Ex. 4, 96:20-97:5. Dr. Dowdy provided the following graphic showing claim limitations ignored by Dr. Hastings (D.I. 427-2, Figure 1).

[redacted]

1. An ~~antisense~~ oligonucleotide of 20 to 31 bases comprising a base sequence ~~that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69),~~ wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the ~~antisense~~ oligonucleotide is a morpholino ~~antisense~~ oligonucleotide, ~~and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.~~

3. Predictability of Exon 53 Skipping ASOs in View of the Wilton Patents

1.10. The exon 53 hot spot identified in the Wilton Patents directly addressed the unpredictability with respect to exon 53 targeting ASOs. D.I. 427-2, ¶¶105, 121-122; Ex. 7, 55:4-10, 58:3-13. A document summarizing the identification of golodirsen states that [redacted] Ex. 12, SRPT-VYDS-0201529.

1.11. [redacted]

1.12. In response to the testing "commissioned" by Dr. Hastings, Dr. Dowdy [redacted] *See* D.I. 427-2, ¶¶75-94. [redacted] *See id.* Combined with select oligonucleotides "commissioned" by Dr. Hastings that conform to the teachings of the Wilton Patents, Dr. Dowdy [redacted] *See id.*, Figure 13 & 14, Table 20. Dr. Dowdy stated that [redacted] *Id.*, ¶211.

[redacted]

II. ***OPPOSITION TO NS'S MOTION #2:*** INFRINGEMENT OF NS PATENTS

NS's summary judgment motion for infringement of the NS Patents is moot in view of the joint stipulation regarding dismissal of certain claims and defenses filed January 8, 2024. D.I. 455, ¶¶1-2 (Sarepta stipulating to voluntary dismissal in part of its defense of no direct and/or no induced and contributory infringement of certain claims of the NS Patents while maintaining all other defenses and counterclaims, including those for invalidity, unenforceability, and no willful infringement of those claims).

[redacted]

III. *OPPOSITION TO NS'S MOTION #3:* BREACH OF CONTRACT

A. Sarepta's Responses to Plaintiff's Concise Statement

1. **Undisputed.**

2. **Undisputed**. However, the term of the MCA has expired with select continuing obligations (e.g., Confidentiality and Non-Use, Section 2). *See* D.I. 2-1 at 3-4, 6.

3. **Undisputed**.

4. **Undisputed**.

5. **Undisputed**.

6. **Undisputed**. The forum selection clause specifically states that "all Potential Actions arising under U.S. law relating to patent infringement or invalidity, and filed within two (2) years of the end of the Covenant Term, shall be filed in the United States District Court for the District of Delaware. . . ." D.I. 2-1 at 7.

7. **Undisputed**. Sarepta does not dispute that the Federal Circuit found the forum selection clause to be unambiguous on its face. However, Judge Stark, in his decision denying NS's preliminary injunction, disagreed. He agreed with Sarepta and held that the interpretation of the forum selection clause is informed by Section 6 of the MCA, statutory rights, and other factors. D.I. 72 at 4-6.

8. **Undisputed**.

9. **Undisputed**.

10. **Undisputed**.

11. **Undisputed**.

12. **Disputed**. Plaintiff mischaracterizes the conclusion of Mr. Jarosz's Rebuttal Report. Mr. Jarosz calculated that the total damages for Plaintiff's breach of contract claim would be [redacted] *See* D.I. 427-10, ¶¶198, 320. Mr. Jarosz calculated this range by

[redacted]

correcting several flaws in the analysis of Mr. Hosfield, NS's damages expert, including the removal of certain "[redacted]" *Id*., ¶¶194-98. However, Mr. Jarosz explains that the $[redacted] is the ceiling for the damages for this claim, and the actual damages could be less. *Id.*

13. **Undisputed**.

14. **Undisputed**. Sarepta does not dispute that NS has unilaterally stipulated to a damages amount of $[redacted] Sarepta disputes that this is the proper measure of damages for NS's breach of contract claim.

[redacted]

B. Sarepta's Concise Counterstatement of Facts

1. Mr. Jarosz's Damages Range

3.1. Sarepta's damages expert, Mr. Jarosz, calculated that if NS were to prevail on its breach of contract claim, damages would be [redacted] D.I. 427-10, ¶¶198, 320. Sarepta does not stipulate that the upper limit of Mr. Jarosz's range constitutes the proper measure of damages for NS's breach of contract claim.

2. NS Materially Breached the MCA

3.2. Sections 1-3 of the MCA define "Confidential Information" and proscribe improper disclosures or uses of confidential information beyond the permitted purposes. Section 2.2, entitled "Obligations of Confidentiality and Non-Use," states among other relevant provisions that:

> The Parties intend and agree that this Agreement, the Proposed Transaction and all disclosures, including all meetings, discussions, correspondence, communications, documents, or other materials exchanged between the Parties made in connection with this Agreement and the Proposed Transaction shall not be submitted, referenced, admitted or otherwise used by the Recipient, its Affiliates, or their respective Representatives against the other Party in any legal action, except in an action to enforce the terms of this Agreement, and shall be treated as conducted in the aid of negotiation and shall be governed by and entitled to the protections and privileges of Delaware Rule of Evidence 408 and Federal Rule of Evidence 408, as well as any and all analogous or applicable privileges or additional limitations on use and disclosure set forth herein. Furthermore, regardless of whether the Proposed Transaction leads to any arrangement or resolution of issues, the fact that these confidential Proposed Transactions occurred shall not be referenced in any legal action currently pending, including but not limited to the EP Oppositions, the JP Actions, or the Potential Actions. Neither Party nor their Affiliates or Representatives shall in any way attempt to place into evidence any document, fact, statement or opinion in any way relating to the Proposed Transaction for any purpose, regardless of whether such document, fact, statement or opinion would be admissible under FRE 408 or any other analogous or applicable privilege.

D.I. 2-1 at 3.

[redacted]

3.3. On July 14, 2021, Nippon Shinyaku filed its original Complaint in this action containing confidential information in violation of the MCA. D.I. 2, ¶¶11, 66, 69. Nippon Shinyaku thus materially breached its obligations under the MCA, Sections 1-3. Ex. 2, 31-34; D.I. 2, ¶¶11, 66, 69.

3.4. In its first set of Rule 12 responsive motions, Sarepta raised an objection to confidential information appearing in Nippon Shinyaku's original Complaint contrary to the terms of the MCA. *See* D.I. 33 at 8-13. Nippon Shinyaku again included the same confidential material in its First Amended Complaint ("FAC"), filed September 10, 2021. *See, e.g.,* D.I. 39 at ¶¶2, 11, 78, 91.

3.5. Sarepta renewed its objection in subsequent Rule 12 responsive motions to such confidential information appearing in Nippon Shinyaku's FAC contrary to the terms of the MCA. D.I. 53; D.I. 54 at 12-18.

3.6. On December 20, 2021, Judge Stark found that Nippon Shinyaku had violated the confidentiality and non-use provisions of the MCA and struck from the FAC the second sentence of paragraph 2 as well as paragraphs 11, 78, and 91 in their entireties. Ex. 2 at 31-34; D.I. 84.

3.7. As Judge Stark found, Nippon Shinyaku "agreed not to hold the parties' confidential communications against Sarepta in future litigation" because the terms of the valid and enforceable MCA had prohibitions against mentioning confidential communications in legal actions. Ex. 2 at 32, 34. But Nippon Shinyaku materially breached the terms of the agreement by including confidential information in its original Complaint and again in its FAC, even after being put on notice of its breach, leading to further briefing, motions practice, and a ruling by Judge Stark striking the confidential information from Nippon Shinyaku's pleading. *Id.*; *see* D.I. 33; D.I. 53; D.I. 54.

[redacted]

IV. *OPPOSITION TO NS'S MOTION #4:* NO ANTICIPATION OF CERTAIN NS PATENT CLAIMS

A. Sarepta's Responses to Plaintiff's Concise Statement

1. **Disputed** in that (1) UWA has not been accused of infringement and has not asserted invalidity counterclaims with respect to NS's patents, and (2) Sarepta has also asserted anticipation by Popplewell '212 against claims 1-2 of the '092 Patent, claim 1 of the '461 Patent, claims 1-2 of the '106 Patent, and claims 1-12 of the '741 Patent; NS does not move for summary judgment with respect to those additional claims.

2. **Undisputed**.

3. **Disputed**. The evidence cited in Plaintiff NS's Statement of Facts – Ex. 11, 123:25-124:3 and D.I. 427-3, ¶50 – does not support the contention "that '212 Popplewell does not ***disclose*** a PMO with the claimed 5'-TEG limitation." Dr. Dowdy merely acknowledges that Popplewell '212 does not "expressly" refer to the 5'-TEG modification, *i.e.*, it does not use the words "5'-TEG." But that does not end the anticipation analysis, because anticipation does not require verbatim disclosure of each claim limitation. *See, e.g., In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) ("the reference need not satisfy an *ipsissimis verbis* test"). As of the earliest possible effective filing date of the claims at issue (August 2011), a POSA would reasonably understand and infer that Popplewell '212 discloses the claimed PMO with a 5'-TEG modification. Popplewell '212 discloses the claimed 25-nucleotide (*i.e.*, "25-mer") "PMO" that is 100% complementary to the (+36+60) region of exon 53 in human dystrophin. *See, e.g.,* D.I. 427-1, ¶299; D.I. 427-3, ¶25. A POSA would know that each "PMO" in Popplewell '212 includes a 5'-end group. D.I. 427-1, ¶113; D.I. 427-3, ¶51. A POSA at the time would also "at once envisage" 5'-TEG as one of three choices of 5'-end group (along with an amide group and a hydroxyl group) for exon-skipping PMOs. *Id*. A POSA would have been particularly interested in a PMO with a 5'-TEG modification

[redacted]

because of the unique advantages of that modification. *See* D.I. 427-1, ¶113 ("In addition to its proven safety profile as reported in Sazani 2010, the TEG modification was believed to confer improved solubility and stability to PMOs.").

[redacted]

B. Sarepta's Concise Counterstatement of Facts

4.1. Popplewell '212 (Ex. 18) discloses a 25-mer "PMO" that is 100% complementary to the (+36+60) region of exon 53 in human dystrophin, as claimed in claim 3 of the '092 Patent, claim 2 of the '461 Patent, and claims 1-4 of the '217 Patent. *See, e.g.,* D.I. 427-1, ¶299; D.I. 427-3, ¶25.

4.2. As of August 2011, a POSA would know that each "PMO" in Popplewell '212 must necessarily include a 5'-end group. *See* D.I. 427-1, ¶113; D.I. 427-3, ¶51.

4.3. As of August 2011, a POSA would "at once envisage" 5'-TEG as one of three choices of 5'-end group (along with an amide group and a hydroxyl group) for exon-skipping PMOs. *See* D.I. 427-1, ¶113; D.I. 427-3, ¶51.

4.4. As of August 2011, a POSA would have been particularly interested in a PMO with a 5'-TEG modification because of the unique advantages of that modification, including improved solubility and stability. *See* D.I. 427-1, ¶113.

[redacted]

V. *OPPOSITION TO NS'S MOTION #5:* NO INEQUITABLE CONDUCT

A. Sarepta's Responses to Plaintiff's Concise Statement

1. **Disputed.** Sarepta, not UWA, has asserted inequitable conduct claims involving the NS Patents. D.I. 328, ¶4. Further, NS oversimplifies and mischaracterizes Sarepta's inequitable conduct claims. Sarepta's claims—and the factual bases for them—span over 130 paragraphs of Sarepta's Counterclaims (D.I. 328, ¶¶96-231), not just the 9 paragraphs cited by NS (*i.e.*, D.I. 328 ¶¶214-218, 227-230). Similarly, Dr. Dowdy's opening and reply reports include over 150 paragraphs related to Sarepta's inequitable conduct claims (D.I. 427-1, ¶¶633-751, D.I. 427-3, ¶¶144-184), not just the 4 cited by NS (*i.e.* D.I. 427-1, ¶¶634-35, D.I. 427-3, ¶¶144, 146). [redacted] *See, e.g.*, D.I. 328, ¶¶97, 173-213, 96-231; D.I. 427-1, ¶¶633-707, 736-748; D.I. 427-3, ¶¶144-184. They further identify testimony and evidence [redacted] (*see, e.g.,* D.I. 328, ¶¶219-226; D.I. 427-1, ¶¶633-748; D.I. 427-3, ¶¶144-184).

2. **Disputed**. Sarepta, not UWA, has asserted inequitable conduct claims involving the NS Patents. D.I. 328, ¶4. Mr. Hirshfeld submitted two expert reports on the issue of inequitable conduct, one dated October 11, 2023 and another dated October 27, 2023. D.I. 427-14, 24:17-20; D.I. 427-8, ¶¶189-213; D.I. 427-9, ¶¶1-3. Mr. Hirshfeld's reports, among other things, respond to

[redacted]

NS's expert Dr. Kamholz's reports on inequitable conduct. *See, e.g.,* D.I. 427-8, ¶¶159-184, 189-213; D.I. 427-9, ¶1. Sarepta also submitted expert reports from Dr. Dowdy that addressed the issue of inequitable conduct. Dr. Dowdy's reports, among other things, identify evidence of and explain why, as a technical matter, the withheld data, information, and references are but-for material and how NS engaged in a pattern of selectively withholding unhelpful data and information from the US and other patent offices that contradicted arguments NS made to the USPTO to obtain issuance of the NS Patents from which a factfinder could infer intent to deceive at trial. *See, e.g.,* D.I. 427-1, ¶¶633-748; D.I. 427-3, ¶¶144-184.

PROSECUTION OF THE '361 PATENT

3. **Undisputed**.

4. **Disputed**. The examiner initially rejected pending claims that were directed to a number of ASOs "all contained within nucleotides 31-61 of exon 53 of the dystrophin gene" and explained that "the specific sequences and modifications recited in the instant claims have been clearly suggested by Popplewell ['212]." D.I. 427-28, at NS00000739-40. The examiner based his obviousness rejection on the Popplewell '212 and Sazani '591 references in view of the Baker and Bennett references as stated in the quoted language. *Id.* at NS00000739. While the examiner block-quoted five paragraphs from Popplewell '212 in his rejection (*id.* at NS00000740-742), the examiner did not specifically note the PMO characteristics identified by NS. Rather, the examiner explained the quoted paragraphs "taught that the same region targeted by the instantly claimed oligomers is superior to other regions of exon 53" (*id.* at NS00000742).

5. **Undisputed.** Sarepta notes that NS does not cite this SOF in its brief.

6. **Disputed**. Sarepta disputes the implication that the examiner only "expressly rejected NS's unexpected superiority argument" as "not persuasive." Br-5 at 3 (citing D.I. 416, ¶6). The examiner rejected all Plaintiff's patentability arguments as not persuasive, including

[redacted]

Plaintiff's arguments that (1) the sequences and modifications recited in the pending claims were not suggested by Popplewell '212; (2) the prior art did not teach the same region targeted by the claimed ASOs is superior to other regions of exon 53; and (3) the claimed "compounds have unexpected properties." D.I. 427-28, at NS00000780-782.

7. **Disputed**. Sarepta admits Plaintiff only made a narrowing amendment to the pending claims to delete one of the two recited SEQ ID NOs. and argued that the sole remaining sequence, SEQ ID NO. 57, showed "superior skipping activity over exemplary oligomers taught in Popplewell ['212] and Sazani ['591], particularly the top performer taught in Popplewell ['212]." *Id*. at NS00000792-794. Sarepta also notes that before this "narrowing amendment," there was a pending dependent claim limited to SEQ ID NO: 57, which the examiner rejected as obvious. *Id*., NS00000757 (claim 23), NS00000775. To the extent Plaintiff implies it further amended the claims, Sarepta disputes such implication as Plaintiff only deleted "SEQ ID NO: 11." D.I. 427-28, at NS00000788.

8. **Disputed**. The examiner did not issue a statement of reasons for allowance when allowing the claims of the '361 Patent. D.I. 427-28, NS00000803-804; D.I. 427-9, ¶29. In responding to the examiner's Final Rejection, Applicant presented, *inter alia*, its "unexpected superiority argument" to argue its claimed SEQ ID NO: 57 had "superior skipping activity over exemplary oligomers taught in Popplewell ['212] and Sazani ['591], particularly the top performer taught in Popplewell ['212]." D.I. 427-28, NS00000792-794. Where an applicant's reply to a rejection explicitly presents reasons why the claims are patentable over the prior art, as a matter of PTO policy, an examiner need not provide such statement if the reasons for allowance are in all probability evidence from the record. D.I. 427-9, ¶29. As Mr. Hirshfeld explains, "[w]ithout a definitive statement by the examiner in the record, it is improper from a USPTO policy and

processes perspective to assume that the examiner wasn't persuaded." D.I. 427-9, ¶29; D.I. 427-28, NS00000793, 803-804.

9. **Disputed**. NS ignores additional data and test results that Dr. Dowdy identified that NS withheld from the PTO. In addition to Dr. Dowdy identified *Compare* D.I. 427-1, ¶¶656-676 *with* D.I. 427-1, ¶¶650-655, 680-700. Sarepta further disputes Plaintiff's implication that Dr. Dowdy opined the withheld data that NS did identify only "'reinforce[d] the trend' of inferiority of NS's claimed AO." D.I. 416, ¶9. Dr. Dowdy provided three reasons why this withheld data was but-for material in paragraph 655 of his opening report. The withheld data showed: (1) D.I. 427-1, ¶655.

10. **Disputed**. NS omits crucial context from Dr. Dowdy's testimony and mischaracterizes his opinions regarding withheld data from Figures 1-8. Dr. Dowdy explained he D.I. 427-3, ¶149. Dr. Dowdy further explained that

[redacted] D.I. 427-3, ¶150 (citing Ex. 8, 95:20-96:4). Dr. Dowdy explained that [redacted] D.I. 427-3, ¶151; *see also* D.I. 427-1, ¶¶690-735. Sarepta also disputes NS's characterization of Dr. Dowdy's deposition testimony. Dr. Dowdy explained that [redacted] *Id.*, 146:5-12.

11. **Disputed**. NS omits key information from Dr. Dowdy's materiality analysis of Sazani 2010. Dr. Dowdy explained Sazani 2010 is material and non-cumulative because it discloses in a ***single reference*** both the atomic structure of a clinical PMO with a 5'-TEG modification and safety and genotoxicity data, including at high doses, which "tells the POSA what a valuable clinical molecule it is." D.I. 427-13, 170:10-173:8. Dr. Dowdy also opined Sazani 2010 is material because, *inter alia*, AVI-4658 was "subsequently included in numerous asserted claims" by NS; it combined with other references "renders obvious the asserted claims of the NS Patents;" Mr. Watanabe and Dr. Takeda recognized Sazani 2010's significance; and Sazani 2010 is noncumulative over Popplewell US '212 and Sazani PCT '586. D.I. 427-1, ¶¶736-748.

12. **Disputed**. Dr. Dowdy testified that Sazani '586 did not "piece[] together" a clinical PMO as done in Sazani 2010, and further did not include the genotoxicity and safety data,

[redacted]

including at high doses, found in Sazani 2010, which "tells the POSA what a valuable clinical molecule" Sazani 2010's compound is. D.I. 427-13, 171:2-173:8; *see also* D.I. 427-1, ¶¶736-748. Dr. Dowdy explained the compound disclosed in Sazani '586 contains "significant" chemical differences, compared to the compound in Sazani 2010. D.I. 427-13, 170:10-173:16, 171:2-18. Mr. Watanabe himself recognized the greater significance of the Sazani 2010 compound (AVI-4658) when he characterized it as a "reference product" for NS's development program prior to the priority date of the NS Patents because, in part, "clinical tests have been conducted" with it. D.I. 427-1, ¶740 (citing Ex. 9, 177:22-178:2, 182:11-183:5; D.I. 331-2 (Ex. BJ), NS0081123 (English Translation)).

13. **Disputed**. NS's cited evidence does not support that "Sazani '586 is the same as the Sazani US 2010/0130591 cited by the examiner in rejecting the claims of the '351 patent." D.I. 416, ¶13. The single sentence footnote in NS's cited expert report states only "'591 Sazani is the US equivalent to WO 2010/048586, i.e., Sazani PCT '586 in the Dowdy Report." D.I. 427-6, 127 n.23. "Equivalent" does not mean "the same," and the footnote does not explain how the two references are "equivalent," let alone "the same." The footnote does not mention, and NS also does not define or identify, "the '351 patent" referred to in NS's Statement of Fact ¶13.

[redacted]

B. Sarepta's Concise Counterstatement of Facts

5.1. Plaintiff omitted citations to paragraphs 219-226 of Sarepta's Counterclaims (D.I. 328) in its SOF ¶1, where Sarepta set forth facts citing testimony and documentary evidence that describe, for example, [redacted] (¶226). D.I. 328, ¶¶ 219-226. Specifically, [redacted] Ex. 9, 40:3-5, 40:17-19, 41:8-15, 213:3-6; *see also* D.I. 427-1, ¶654 & n.28 (and evidence cited therein). [redacted] Ex. 9, 42:3-11, 44:4-7, 181:1-24; *see also* D.I. 427-1, ¶654 & n.28 (and evidence cited therein). [redacted] Ex. 9, 43:15-23; 44:8-13; *see also* D.I. 427-1, ¶654 & n.28 (and evidence cited therein). [redacted] Ex. 9, 214:20-215:4; *see also* D.I. 427-1, ¶654 & n.28 (and evidence cited therein). [redacted] *See* Ex. 9, 112:15-21 (Fig. 9), 113:6-17 (Fig. 10), 116:20-117:8 (Fig. 11), 117:25-118:16 (Fig. 12), 119:23-120:6 (Fig. 13), 121:3-13 (Fig. 14), 122:10-17 (Fig. 15), 126:5-15 (Fig. 16),

[redacted]

128:20-129:2 (Fig. 17); *see also id.* at 82:1-10, 108:17-109:24, 111:17-112:2, 114:2-5, 123:14-124:4, 122:18-123:4, 124:6-22, 125:22-126:4, 126:16-127:2; D.I. 331-1 (Ex. BB); D.I. 331-1 (Ex. BC); D.I. 331-1 (Ex. BD); D.I. 331-1 (Ex. BE); D.I. 331-1 (Ex. BF); D.I. 331-1 (Ex. BG), NS00066517; D.I. 331-1 (Ex. AW), Table 1; *see also* D.I. 427-1, ¶¶650-655 (and evidence cited therein). [redacted] (*i.e.*, "PMO-G"). Ex. 9, 29:10-25, 208:8-210:25, 211:10-15; D.I. 331-3 (Ex. BR); D.I. 331-1 (Ex. BA); D.I. 331-3 (Ex. BQ); Exs. 22 & 23; D.I. 331-3 (Ex. BP), pp. 29-34; *see also* D.I. 331-1 (Ex. AW), Table 1; *see also* D.I. 427-1, ¶¶656-668 (and evidence cited therein)

5.2. NS relied on data from at least Figure 16 during prosecution of the NS Patents, specifically prosecution of the '361 Patent that is a grandparent to the remaining NS Patents, to argue its claimed ASO had "unexpectedly superior" skipping effects over the ASOs taught in the Popplewell '212 and Sazani '591 prior art references. D.I. 427-28, NS00000761, -793 ("Furthermore, Figures 16-17 (corresponding to data in Test Example 6) show that the oligomer having the nucleotide sequence of SEQ ID NO: 57 (H53_36-60) displays a higher level skipping activity tha[n] that having the nucleotide sequence of SEQ ID NO: 11 (H53_32-56). Thus, the recited oligomers consisting of the nucleotide sequence of SEQ ID NO: 57 also have superior skipping activity over exemplary oligomers taught in Popplewell ['212] and Sazani ['591], particularly the top performer taught in Popplewell ['212]. Applicants submit that this superiority is unexpected."); *see also* D.I. 427-1, ¶¶221-230.

5.3. [redacted]

[redacted] Ex. 9, 124:6-22; *see also* D.I. 427-1, ¶¶651-655.

5.4. [redacted] Ex. 9, 125:22-126:4; *see also* D.I. 427-1, ¶¶642, 684, 686 [redacted], ¶¶651-655 [redacted].

5.5. [redacted] *See supra* RSOF ¶5.1. As Dr. Dowdy explains, [redacted] D.I. 427-1, ¶¶656-668 (and evidence cited therein); *see also* D.I. 427-28, NS00000793.

5.6. Sazani 2010 is not cumulative to prior art of record in the prosecution of the NS Patents. *See* D.I. 427-1, ¶¶744-748; D.I. 427-3, ¶¶162-181 9 (and evidence cited therein). Sazani 2010 contained—all in one reference—additional disclosures to those of the prior art of record, including genotoxicity and pharmacology safety studies. *See* D.I. 427-1, ¶¶736-748 (and evidence cited therein); Ex. 11, 166:14-168:3, 170:10-173:8; *see also supra* Response to SOF ¶¶11-13. Unlike the prior art of record, Sazani 2010 also disclosed the full atom-by-atom structure of an exon skipping PMO in clinical trials for the treatment of DMD. D.I. 427-3, ¶¶165, 168.

5.7. [redacted]

[redacted] D.I. 331-2 (Ex. BM) (which includes the online version of Sazani 2010 as an attachment); Ex. 9, 177:22-178:2, 182:11-183:5, 183:8-184:3; D.I. 331-2 (Ex. BJ), NS0081123 (English Translation); *see also* D.I. 427-1, ¶¶736-748 (and evidence cited therein); *supra* Response to SOF ¶12.

5.8. [redacted] of NS's patents' specification that he drafted, nor ensuring it was otherwise provided to the PTO. Ex. 9, 42:3-11, 44:4-7, 181:1-24; *see also* D.I. 427-1, ¶¶654 & n.28, 736-748 (and evidence cited therein).

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January 12, 2024

CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 12, 2024, upon the following in the manner indicated:

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